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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 22

Application Number: 08/981,665
Filing Date: 05 November 1997
Appellant(s): STAN CIPKOWSKI

Edmund M. Jaskiewicz
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed 13 June 2000.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is substantially correct. A correct statement of the status of the claims is as follows:

This appeal involves claims 16-19.

Claims 1-15 been canceled.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is deficient because: it fails to refer to the specification by page and line number, or to drawing figures, as required by 37 CFR§1.192(c)(5); there is no support in the specification for each test strip being "fully protected" and "prevented" from coming into human contact without the necessity for sealing or enclosing the individual test strips as asserted by appellant because there are openings in the front surface of the test card exposing the test strips; and, there is nothing in the specification to support appellant's assertion that the construction of the test card of the invention does anything to avoid contact between the person being tested and the fluid sample to be tested, or the person being tested and the person carrying out the test.

A correct statement of the summary of invention is as follows:

The invention is a drug of abuse test card having an end which is inserted into a fluid sample, usually urine, to detect the presence of a drug of abuse in the sample. The test card carries thereon one or more immunoassay test strips disposed between the front and rear surfaces of a thin flat member such that the ends of the test strips terminate short of the ends of the test card and are enclosed therein (page 12, lines 18-21; Figs. 1, 3, 9, 11, 12). The immunoassay test strips are mounted on the card so that a first portion of each test strip, at the end of the test card which is inserted into the fluid sample, contacts and receives the fluid sample at a sample portion of the test strip and a second portion of the test strip spaced apart from the sample portion, comprising a test portion, visually indicates presence or absence of a selected drug of abuse (page 5, line 19, through page 6, line 1; page 12, lines 4-9; page 13; Figs. 1, 3 and 9-14). In these test strips, the fluid sample moves by capillary action through the material of each test strip from the first sample portion of the strip to the second or test portion of the strip in what may be described as a continuous flow, or as generally referred to in the industry as "lateral flow" (page 13, lines 3-22). Access to each test strip is through a pair of openings in the front surface of the test card spaced longitudinally to register with and expose the sample and test portions of each of the test strips (page 11, lines 17-20; page 12, lines 4-9 and 15-16; Figs. 1 and 9-14). In use, the test card is usually inserted longitudinally through an opening, generally a slit in the top of a container having the fluid sample therein, until the first portion of the test strips contacts the fluid sample (page 4, lines 21-25; page 10, lines 10-15).

The construction of this test card is such that proper contact of a plurality of test strips on the test card with the fluid sample is ensured and reading of the visual results is facilitated. There is no necessity for any dispensing or application of the fluid sample to be tested onto a test strip.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 16-19 stand or fall together because appellant's brief includes a statement that this grouping of claims stands or falls together.

(8) Claims Appealed

A substantially correct copy of appealed claim 16 appears on page 10 in the Appendix to the appellant's brief. The minor errors are as follows: in claim 16, at lines 1 and 6, "immunoassay" should be --immuno assay--.

(9) Prior Art of Record

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

5,238,652	SUN et al.	08-1993
4,518,565	BOGER et al.	05-1985
5,119,830	DAVIS	06-1992
5,500,375	LEE-OWN et al.	03-1996
5,712,172	HUANG et al.	01-1998
5,441,698	NORELL	08-1995

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 16-19 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over Sun et al (US 5,238,652) in view of Boger et al (US 4,518,565), Huang et al (US 5,712,172), and either of Davis (US 5,119,830) or Lee-Own et al (US 5,500,375). Note that Norell has been withdrawn from the statement of the rejection as the reference teachings are drawn to previous limitations and/or embodiments no longer found in the claims on appeal. The withdrawal of this reference does not constitute a new ground of rejection.

Sun et al teach membrane strips for competitive immunoassay of drugs of abuse (e.g. columns 5-6) and that analytical test devices incorporating the strips for such drug of abuse analytes may be configured in a parallel arrangement for simultaneous testing of multiple analytes

(e.g. Fig. 3), at least five analytes in a single device being preferred (e.g. column 2). In contrast to the invention as instantly claimed, the reference teaches moisture impervious housing(s), such as welded plastics, for supporting the membrane strips, each housing having an opening for introduction of a body fluid sample (e.g. column 5, lines 14-20), rather than alternative supports also having openings exposing the test portions of the strips.

Boger et al teach a holder for dip-and-read reagent test strips ("devices"), including those for immunochemical, diagnostic, or serological tests (e.g. column 2, lines 58-62), which facilitates contact of the strips with sample material, either by dipping of the entire holder in sample or dispensing sample thereon (e.g. ¶ bridging cols. 4-5), and presentation of the sample-contacted strips to a result measuring instrument (e.g. column 5, lines 3-7 and 41-45). The holder can be constructed of any suitable material including coated cardboard and comprises at least a base member, which may have ridges or other means which facilitate the preferred parallel alignment of the strips, and a top member, which has openings to expose the strips for sample application and taking measurements of results (see e.g.: columns 3-4; ¶ bridging columns 2-3). The depicted rectangular shape is preferred to permit the maximum number of strips to be inserted into a holder of the smallest possible dimensions (e.g. col. 4, lines 24-32). The members may be provided separately or as a foldable assembly. The strips may extend beyond the holder (Figs. 2-3) or the holder can be made long enough to accommodate the strips in their entirety (column 4, lines 54-58). The holders may be either disposable or reusable and may be used for storage of test strips

after their use for testing (e.g.: col. 2, lines 14-19; col. 5, lines 50-53). Boger et al do not specifically teach strips for immunoassay of drugs of abuse.

Huang et al teach sandwiching, by lamination, of an immunochromatographic device between a backing material and a plastic covering material to obviate the need for a plastic housing. The covering material partially covers the device or encompasses one or more openings or holes to provide an exposed sample receiving region (e.g. Figs. 1 and 4) and, if not of a clear material, an additional window, gap, or hole is provided in the covering for results viewing (e.g. col. 7, lines 23-31). Illicit drugs are suggested analytes for detection with the invention (see e.g. column 4). The reference does not specifically teach housing multiple devices for a number of analytes in a single assembly.

Davis teaches an analytical specimen cup having a chemical test "strip" with a plurality of "pads" for multiple analytes, in one embodiment the "strip" being the size and shape of a card (see e.g. Figure 6) having the multiple analyte "pads" arranged in parallel.

Lee-Own et al disclose laminated immunochromatographic devices for detection of analytes, including drugs of abuse (e.g. columns 5 or 8). Immunochromatographic assay means, such as impregnated nylon membrane strip(s) (e.g. column 5), are laminated between sealing means and support means, such as adhesive films or plastic sheets (columns 7-9). The reference teaches transparent plastic for the sealing/support means, thereby exposing the membrane strip(s) for viewing as the reference teaches that observation of the result through a test window is required of such devices (see e.g. col. 1, lines 55-65). Lamination would be expected to provide a

slot-like "recess" in the films and/or sheets housing the strip(s) as depicted in any of Figs. 2, 3, 9, or 11. Multiple membrane strips may be configured in a single device to allow for multiple assays (e.g. column 7, lines 21-23). The device may be incorporated into a sample collection vessel such as a urine collection vessel (e.g. column 8). In use, the end of the membrane strip(s) is/are exposed by cutting the laminate or peeling off a protective cover and the membrane(s) contacted with sample by dipping into, immersion into, or application thereto of sample.

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have supported the test strips of Sun et al on any known and conventional alternative support/holder, such as those taught by Boger et al or Huang et al, because one would have had ample motivation to select from known and conventional alternative support/holder components with the expectation that such a known support would perform its desired support/holder function. If a support/holder such as that of Boger et al was selected for multiple test strips as desired by Sun et al it would have been obvious to have formed the ridges, defining parallel slots, in the base member for strip alignment as taught in Boger et al by any conventional means because one of ordinary skill would have expected a conventional means such as lamination of multiple layers, molding, or cutting, to form the desired ridges and slots therein. One would have had ample motivation to have selected from among such conventional known techniques with an expectation of success. It would have been an obvious matter of design choice to have adhered the test strips to the holder device in those embodiments where either a disposable or storage holder were contemplated, as is conventional in the art, to prevent shifting of the test

strips in the holder device. It would have been further obvious to have provided the support/holder of Sun et al in view of Boger et al with windows, openings, gaps, or holes for sample application and viewing, as is conventional and required for such supports/holders in order to apply sample to the test strips and view results on the test strips, especially immunoassay test strips, as taught by any of Boger et al, Huang et al, Lee-Own et al, or Sun et al. If necessary, it would have been obvious to have housed multiple devices for a number of analytes as desired by Sun et al in parallel in a single support assembly of a design such as that of Huang et al as is conventional in the art as taught in any of Boger et al, Lee-Own et al, or Sun et al. It would have been further obvious to one of ordinary skill in the art at the time the instant invention was made to have provided the multiple membrane strip device of Sun et al, as modified, in the size and shape of a card because one would have been motivated to provide such a size and shape to the device to facilitate insertion, as suggested by the dip and read mode of operation taught in Boger et al or Lee-Own et al, or incorporation of the device into a urine collection vessel either of conventional design as disclosed in Lee-Own et al or of a design such as that of Davis.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

(11) Response to Argument

In response to appellant's arguments that there are no specific suggestions to combine the references, the examiner recognizes that references cannot be arbitrarily combined and that

obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Nomiya*, 184 USPQ 607 (CCPA 1975); *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). However, there is no requirement that a motivation to make the modification be expressly articulated. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. *In re McLaughlin*, 170 USPQ 209 (CCPA 1971). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. *In re Bozek*, 163 USPQ 545 (CCPA 1969). In this case, for the reasons of record, ample motivations to substitute a known and conventional holder such as that taught by Boger et al or by Huang et al, in view of other conventional elements in the manufacture of such holders taught by the cited references, for supporting the drug of abuse test strips of Sun et al have been provided.

In response to appellant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Arguments against individual aspects of the references which were not relied upon in the rejection and which do not serve to teach away from the invention as a whole, such as particular structural elements of various

particular embodiments of the housings/holders of Sun et al or of Lee-Own et al or of Boger et al, were not found persuasive. For example, appellant urges that Sun et al teach an embodiment wherein sample flows through a passage of a device housing before coming in contact with the lateral flow immunoassay test strip therein. This is not found persuasive as the reference teaches other embodiments in which an absorbent pad is found at the sample application opening of the housing and the test membrane, having the colored latex spheres sensitized or coated with detecting antibodies impregnated thereon in close proximity to the opening and the absorbent pad, is implicitly in close proximity to or in contact with the opening and absorbent pad. Indeed, Huang et al teach that in such lateral flow immunoassay test strips the sample receiving pad is in fluid contact, by overlap, abutment, or continuity, with the other regions of the test strip. There is no disclosure in appellant's specification regarding whether the instant test strip does or does not include an absorbent pad at the sample receiving portion. The reference of Sun et al is cited primarily for its specific disclosure of membrane strips containing reagents for competitive immunoassay of drugs of abuse, i.e. the "immunoassay means" on the immunoassay test strips disclosed by appellant's specification, and not for the particularities of the housings chosen by the reference for the test strips.

Appellant urges that the housing of Sun et al requires sample application thereto. This is not found persuasive as the housing of Sun et al is not relevant to the instant grounds of rejection and dipping into, immersion into, or application thereto of sample are known alternative means of test strip contacting with sample (see e.g. Boger et al or Lee-Own et al).

Appellant urges that the test devices in Sun et al and Boger et al are wholly dissimilar. This is not found persuasive as the references are found to teach alternative housings/holders for immunoassay test strip devices. Notwithstanding appellant's arguments to the contrary, Boger et al teach the general applicability of their holder for "dip-and-read" test devices and the disclosure is not seen to limit the reagent test pad devices for use therein. There is no limitation found in the reference that the color change occur at the sample receiving portion of the test devices of Boger et al as would appear appellant's assertion. There is no disclosure which would teach away from the use of a lateral flow immunoassay device in the holder of the reference as would appear to be argued by appellant, as the reference suggests the use of immunoassay devices in the holder and such devices as taught in Sun et al using colored latex clearly result in a color change at the test portion of the device.

Appellant urges that Boger et al only teach a test strip holder wherein the "handle" of a test strip therein extends from the top of the holder. This is not found persuasive in view of the cited reference teachings that the holder can be made long enough to accommodate the strips in their entirety (column 4). Appellant's assertion that removal of the test strips for measurement is required by Boger et al was not found persuasive because the reference clearly teaches a holder in which openings are provided for sample application and for taking assay measurements in a photometric apparatus, if desired, on the multiple test strips preloaded in the holder. Moreover, the holder may be disposable and/or used for long term storage after use in testing, embodiments which would clearly be inconsistent with appellant's arguments.

Appellant urges that all of the openings disclosed in Boger et al are intended only for applications of samples. This is not found persuasive as the reference teaches taking results measurements with the test strips in the holder and it would have been obvious to have provided a means for doing so because this is not only taught in the reference but is also required and conventional in the art. Again, there is no limitation found in the reference that the color change occur at the sample receiving portion of the test devices of Boger et al as would appear appellant's assertion. As taught in Huang et al, any conventional alternative such as an additional window, gap, or hole is necessary in the covering of a immunoassay test strip for results viewing in addition to that for sample application. Boger et al clearly teach the use of their holder for immunoassay test strips and it would have been obvious to have provided not only the required sample application window, gap, or hole but also the required additional result viewing window, gap, or hole as was known to the art. Indeed, as seen in Fig. 3, Boger provides a holder for a plurality of "single pad reagent test devices" in which a single opening is disclosed, but which appears to depict a number of openings in the top of the holder registering with the "single pad reagent test devices." Appellant argues that the unlabelled "rectangular structures" are not second openings because there is no indication in the specification what the second unlabelled "rectangular structures" are. This is not found persuasive because it would have been obvious from the drawing that the second "structure" was an opening exposing the reagent test strips and, in view of common knowledge in the art, it would have been obvious to one of ordinary skill in the art that such an opening could be used for result viewing as required on immunoassay test

strips known to the art wherein sample application and result viewing are in different portions of the test strip.

Appellant urges that Huang et al only teach test strips similar to those as used in the instant invention. This is not found persuasive in view of the laminated holder taught in the reference. As also set forth, multiple membrane strips configured in a single device to allow for multiple assays of a single sample was also known and obvious to the art, including for laminated devices in view of at least Lee-Own et al.

Appellant urges that Davis does not disclose submersion of the test device into a sample. This is not found persuasive as the argument is drawn to the intended use of the card and is not found to distinguish the instant invention from a device of the size and shape as required by Davis.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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August 28, 2000

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